UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

VERAX BIOMEDICAL INC.,

Plaintiff,

v.

AMERICAN NATIONAL RED CROSS,

Defendant.

Civil Action No.: 1:23-cv-10335-PBS

Leave to File Reply Granted on 5/30/2023

AMERICAN NATIONAL RED CROSS'S REPLY IN SUPPORT OF ITS MOTION TO DISMISS THE COMPLAINT PURSUANT TO FED. R. CIV. P. 12(B)(6)

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INTRODUCTION

Verax's opposition confirms that its case arises entirely from the fact that federal regulations coupled with innovation have rendered its aftermarket PGD*prime* test commercially less attractive to some hospitals. Federal law requires the Red Cross to perform bacterial mitigation on platelets and gives it only three options to do so. The Red Cross picked the innovative new technology that it believed best maximizes platelet safety and availability (pathogen reduction technology or PRT). The fact that Verax wishes the Red Cross had forgone this safety innovation and chosen something else does not state any violation of law. If Verax wants to solve its commercial problem, it should innovate rather than waste the limited resources of the Red Cross—a federal instrumentality that Congress has tasked with critically important national and international responsibilities—with a baseless claim. The Court should dismiss the complaint in its entirety.

I. ALL OF VERAX'S ANTITRUST CLAIMS FAIL: VERAX IGNORES THE CLEAR INTENT OF CONGRESS THAT THE RED CROSS IS NOT A "PERSON" SUBJECT TO SHERMAN ACT LIABILITY

Verax fundamentally misunderstands the law and facts governing whether an entity is a "person" subject to the Sherman Act. Congress has statutorily designated the Red Cross as a "[f]ederally chartered instrumentality of the United States," 36 U.S.C. § 300101(a), and made clear that it has all "the rights and obligations consistent with that status."[1] *No court has ever found that an entity that Congress formally designated a federal instrumentality for all purposes is a "person" under the Sherman Act*. Verax fails to grapple with this dispositive point. Instead, it

[1] American National Red Cross Governance Modernization Act of 2007, H.R. 1681, at Sec. 2(a)(7), (b)(4)–(5), 110th Cong. (2007) (hereinafter "2007 Red Cross Act").

makes five arguments, none of which account for Congress's formal designation of the Red Cross as a federal instrumentality or the relevant Supreme Court precedent interpreting the Sherman Act.

First, Verax argues that the Red Cross is a "person" under the Sherman Act because Congress waived the Red Cross's sovereign immunity. Opp. (ECF No. 23) at 6–7. That argument ignores the law. The Supreme Court and D.C. Circuit have both made clear in *Flamingo* and *Sea-Land* respectively that the "person" question is entirely distinct from sovereign immunity.[2] *U.S. Postal Serv. v. Flamingo Indus. (USA) Ltd.*, 540 U.S. 736, 743–48 (2004); *Sea-Land Serv., Inc. v. Alaska R.R.*, 659 F.2d 243, 244–45 (D.C. Cir. 1981). In both cases, Congress had waived the applicable sovereign immunity, but that did not end the analysis. *Id.* Rather, both courts went ahead and analyzed whether Congress intended for the defendants in those cases to nevertheless be "persons" under the Sherman Act and concluded it did not. *Id.* As the Supreme Court noted in *Flamingo*, 540 U.S. at 744, "[a]n absence of immunity does not result in liability if the substantive law in question [here, the Sherman Act] is not intended to reach the federal entity." As such, Congress's decision to waive the Red Cross's sovereign immunity is relevant in just one respect: it demonstrates that *Congress clearly believed the Red Cross to be a sovereign arm of the United States for which waiver was necessary*. That is simply further *statutory* evidence that the Red Cross is not a "person" under the Sherman Act. Statutory evidence matters because the Supreme Court has directed that the "person" issue is fundamentally a question of statutory interpretation.

Because the Red Cross is not asserting a sovereign immunity defense, *Marcella v. Brandywine Hosp.*, 47 F.3d 618 (3d Cir. 1995) (cited in Opp. at 7, 9) is not relevant here. That

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[2] As Verax notes, Congress chose to waive the Red Cross's sovereign immunity by giving it the power to "sue and be sued in courts of law and equity." 36 U.S.C. § 300105(a)(5). The Red Cross is not asserting a sovereign immunity defense to Verax's antitrust claims. As such, it did not waive anything by failing to raise sovereign immunity in its opening brief. Opp. at 7 n.3.

case addressed whether, despite Congress's waiver of its sovereign immunity *for suit*, the Red Cross was nonetheless still entitled to sovereign immunity from trial by jury. *Id.* at 621. *Flamingo* and *Sea-Land* make clear that questions of sovereign immunity are fundamentally different from whether the Red Cross is a "person" under the Sherman Act. *Flamingo*, 540 U.S. at 743–48; *Sea-Land*, 659 F.2d at 244–45. Different laws require different tests to determine how to treat federal entities. *See Marcella,* 47 F.3d at 624 (deciding whether granting Red Cross sovereign immunity from jury trial would be "inconsistent with, or interfere with, the role outlined in the organization's charter"). *Flamingo* sets forth the specific legal framework for the Sherman Act. In any event, because *Marcella* pre-dated Congress's 2007 amendment to the Red Cross's statutory designation to make it a federal instrumentality, there is no way to know whether that court would reach the same outcome today. Even without the clarity Congress provided in 2007, the Third Circuit still noted that the sovereign immunity question was "not a simple one" and that other courts had reached the opposite result for the Red Cross. *Marcella,* 47 F.3d at 621 & n.4.

Second, Verax ignores the fact that Congress gave the Red Cross the formal statutory designation of a "[f]ederally chartered instrumentality of the United States," 36 U.S.C. § 300101(a), and instead urges the Court to analyze the "person" issue as if the Red Cross were a mere corporation because the Red Cross supposedly "is organized as a corporation." Opp. at 8. That is wrong as a matter of law and statutory interpretation.

The Supreme Court has ruled that to determine whether a "federal entity" is a "person" under the Sherman Act requires an examination of "the statutes that create and organize" the entity because the issue is one of Congressional intent. *Flamingo*, 540 U.S. at 744–46. The "statutory designation" indicates whether Congress intended it to be an entity "existing outside the Government" for Sherman Act purposes. *Id.* at 746. The Supreme Court concluded that the Postal

Service's designation as an "independent establishment of the executive branch of the Government of the United States" is "not consistent with the idea that [the Postal Service] is an entity existing outside the Government." *Id*. at 746. The Red Cross's designation as a "[f]ederally chartered instrumentality of the United States" clearly is not consistent with that idea either.

Against this backdrop, adopting Verax's position would be unprecedented. No court has ever found that an entity that Congress formally designated a federal instrumentality for all purposes is a "person" under the Sherman Act. The reason is straightforward. Congress's "statutory designation" of a federal instrumentality renders that entity not a "person" under the Sherman Act absent "an express statement from Congress that the [federal entity] can be sued for antitrust violations despite its status[.]" *Id.* at 746–47; *Sea-Land*, 659 F.2d at 247 (courts should not subject federal instrumentalities to the Sherman Act absent a "clear statement" from Congress). Thus, where, as here, the statute makes clear that the party is a federal instrumentality, it is not a "person" amenable to a Sherman Act suit unless Congress has expressly said so. Congress has not made any "express statement" that the Red Cross "can be sued for antitrust violations despite its status" as a federal instrumentality. *Flamingo*, 540 U.S. at 746–47. This is a dispositive point.

Third, Verax's attempt to shoehorn this case into the facts of *McCarthy v. Middle Tenn. Elec. Membership Corp.,* 466 F.3d 399 (6th Cir. 2006) (*see* Opp. at 8) is misplaced. If anything, that case supports the conclusion that the Red Cross is *not* a "person." The Sixth Circuit relied on Congress's formal statutory designation of the federal entity at issue (the Tennessee Valley Authority) as a federal corporation. *McCarthy*, 466 F.3d at 414 (citing 16 U.S.C. § 831). The Court of Appeals noted that in *Flamingo*, the Supreme Court did not decide, one way or the other, whether a federal corporation could be a "person" under the Sherman Act. *Id*. at 413–14. After commenting that it was "not an easy question," the Sixth Circuit nevertheless found that the TVA

was a "person," but this conclusion was not germane to the outcome because the court went on to hold the TVA was entitled to antitrust immunity for another reason. *Id.* at 414 (holding TVA immune from antitrust liability because "concerns about competition would conflict with the fulfillment of TVA's purpose" under its federal statute). Confirming the context-specific nature of *McCarthy*, the Sixth Circuit had previously held that the Federal Reserve Banks were not "persons" under the Sherman Act even though they were federal corporations. *Jet Courier Servs., Inc. v. Fed. Rsrv. Bank of Atlanta*, 713 F.2d 1221, 1228 (6th Cir. 1983) (Federal Reserve Banks not subject to the Sherman Act because they "perform[] a vital governmental role").

Tellingly, one year ***after*** the ambiguity *McCarthy* created about federal corporation status, Congress amended the Red Cross charter to formally designate it as an "instrumentality of the United States" and not just a mere federal corporation. This was the first time Congress amended the Red Cross's statutory designation in over 100 years. In doing so, Congress made explicit that the Red Cross has all "the rights and obligations consistent with [its federal instrumentality] status." 2007 Red Cross Act at Sec. 2(a)(7), (b)(4)–(5). Out of the 94 federally chartered non-profits in Chapter 36 of the United States Code, the Red Cross is the ***only one*** whose designation Congress changed after *Flamingo* and *McCarthy*. *See* 36 U.S.C., Subtitles I, II, III. The rest remain only federally chartered corporations.[3] *Id.* The Court must presume Congress's choice was "informed [rather] than unconsidered" (*Flamingo*, 540 U.S. at 746) when it amended the Red Cross's designation in 2007 to confirm its federal instrumentality status. Because the "person" question turns on Congressional intent, the Court cannot, as Verax urges, ignore that Congress amended the Red Cross's statutory designation—for the first time in 100 years—three years after

[3] Congress even gave the Red Cross its own separate Subtitle of Chapter 36 of the U.S. Code where it stands alone as the only "Treaty Obligation Organization[]." 36 U.S.C., Subtitle III.

Flamingo ruled that statutory designation is key to the "person" analysis, and one year after *McCarthy* suggested that being solely designated a mere federal corporation might not be enough.

Fourth, in a last-ditch effort to distinguish *Flamingo*, Verax argues that the Red Cross is not identical in all respects to the Postal Service. Opp. at 9. But the Red Cross does not have to be. *Flamingo* did not create a checklist of features that every federal entity must meet. Instead, it set forth the analytical framework that courts must look to "the statutes that create and organize" the entity, and, most importantly, to the entity's "statutory designation" to discern Congress's intent. 540 U.S. at 744, 746. If it is not clear that the entity is a federal instrumentality from its "statutory designation" alone then other features of the statute can inform the entity's status. *Id.* at 746–48. The Supreme Court looked to other aspects of the Postal Service statute in order to confirm that it was properly treating the designation of "an independent establishment of the executive branch" as the functional equivalent of a federal instrumentality instead of "an entity existing outside the Government." *Id.* at 746–47 (noting statutory features that were "consistent" with "conclusion" based on designation). There is no need to go looking for such confirmation here because Congress unambiguously said that the Red Cross *is* a federal instrumentality.

Verax's argument ignores that, for decades prior to *Flamingo,* courts had unanimously agreed that the United States and its federal instrumentalities were not subject to the Sherman Act.[4] That was uncontroversial then and remains uncontroversial today. The only relevant issue ever in dispute in those pre-*Flamingo* cases was whether a particular entity should qualify for federal instrumentality status when Congress had not formally designated it as such. It was in *those*

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[4] *See, e.g., Champaign-Urbana News Agency, Inc. v. J.L. Cummins News Co.*, Inc, 632 F.2d 680, 682 (7th Cir. 1980); *Sea-Land,* 659 F.2d at 244–47; *Jet Courier,* 713 F.2d at 1228; *Sakamoto v. Duty Free Shoppers, Ltd.,* 764 F.2d 1285, 1288–89 (9th Cir. 1985); *IT & E Overseas v. RCA Glob. Commc'ns, Inc.*, 747 F. Supp. 6, 14 (D.D.C. 1990).

circumstances that courts examined various statutory features of the entity to reach a conclusion. That was the case for the Guam Telephone Authority in *RCA Global,* the Army and Airforce Exchange Service in *Champaign-Urbana News Agency*, the Alaska Railroad in *Sea-Land,* the Guam Airport Authority in *Sakamoto*, and the Federal Reserve Banks in *Jet Courier*. *See supra* n.4 (citing cases). It was also the case in *Flamingo.* 540 U.S. at 746–47. But here there is no ambiguity about the Red Cross's status as a federal instrumentality and there can be no dispute that Congress intends it to have all the rights of that status. Congress said so expressly. Thus, there is no need to look at other features of the Red Cross statute to try to infer Congress's intent.

Nonetheless, even if Congress's statutory designation alone did not end the analysis for the Red Cross, and the Court went on to examine other features of the Red Cross statute, it would still conclude the Red Cross is not a "person." Other aspects of the statute show that Congress gave the Red Cross (a) "nationwide, public responsibilities" and (b) "different goals, obligations, and powers from private corporations." *Id*. at 747. All of that coupled with Congress's explicit statutory designation confirms the Red Cross is not a "person."

For example, Congress gave the Red Cross both national and international public responsibilities (*id*.), such as (1) calling on the Red Cross to provide humanitarian relief for both national and international disasters (36 U.S.C. § 300102(4)); (2) using the Red Cross to fulfill certain of the country's international treaty obligations, including Geneva Convention obligations (*id.* §§ 300102(1), 300105(b)); (3) relying on the Red Cross to provide critically important services and support to the U.S. Armed Forces (*id.* §§ 300102(1), 300102(3)); and (4) carrying out a system in times of peace to mitigate suffering, including, among other things, by ensuring life-saving blood products are available for national calamities (*id.* §§ 300102(4), 300102(5)).

The Red Cross also has "different goals" from private enterprise because it is a non-profit that does not act in any manner by desire for gain. *Flamingo*, 540 U.S. at 747 (noting that non-profit status was the "most important difference" between the goals of public and private enterprise for purposes of determining whether an entity not statutorily designated an instrumentality qualified as a "person"); *see generally* 36 U.S.C. § 300102. Similarly, the Red Cross has different "obligations" because, for example, the Red Cross (a) has both national and international relief obligations, including fulfilling U.S. international treaty obligations (36 U.S.C. §§ 300102(1), 300105(b)); (b) has its activities and finances audited by the Secretary of Defense and reported to Congress (*id.* § 300110); (c) maintains an Office of the Ombudsman that reports to Congress (*id.* § 300112) and (d) has a Chairman that the President of the United States appoints and can remove (*id.* § 300104(a)(3)). And Congress gave the Red Cross different "powers" because, unlike private entities, Congress provided federal court jurisdiction for *all* suits involving the Red Cross. *Id.* § 300105(a)(5); *Am. Nat'l Red Cross v. S.G. and A.E.*, 505 U.S. 247, 257 (1992).

Contrary to Verax's suggestion (Opp. at 9), it would be wholly improper to parse the Red Cross's operations and conclude that some aspects qualify for "person" status and others do not. No court has ever done the analysis like that. The relevant question is whether Congress made the Red Cross as an entity a "person." *Cf. RCA Glob.*, 747 F. Supp. at 14 (it is irrelevant whether entity is acting beyond the scope of its enabling legislation because "federal instrumentality doctrine provides *absolute* immunity") (emphasis in original). Indeed, in *Flamingo*, the Supreme Court acknowledged that the Postal Service independently operated some for-profit lines of business; however, the Court did not analyze those businesses separately. 540 U.S. at 747–48. Instead, it found the Postal Service *as an entity* was not a "person." *Id.* at 747–48.

It also does not matter, as Verax claims (Opp. at 9), that the Red Cross sets prices for blood products. The fact that the Postal Service did not have the power to set most of its prices by itself, and instead set most of them in conjunction with another independent agency, was not critical to the result in *Flamingo.* 540 U.S. at 747–48. The Supreme Court made clear that the mechanics of how the Postal Service set its prices was not as important as its substantive approach to business generally; *i.e.*, as a non-profit, its "price decisions are governed by principles other than profitability." *Id.* at 747. The same is true for the Red Cross.

Similarly, the fact that the Red Cross adheres to a principle of "independence," *i.e.,* independence from partisan controls (Opp. at 9) is not relevant here. The Postal Service was created as an "*independent* establishment" specifically to "reduce political influences on its operations," but the Supreme Court still found it not to be a "person." *Flamingo*, 540 U.S. at 740 (emphasis added); *id*. at 746 ("The PRA gives the Postal Service a high degree of independence from other offices of the Government, but it remains part of the Government.").

Last, Verax argues that "it would be poor public policy to extend antitrust immunity to entities like [the Red Cross]." Opp. at 9. But that argument is for Congress, not courts. In *Sea-Land*, the plaintiffs likewise argued that "it is anomalous and unfair for a United States instrumentality to escape the regimen of antitrust laws the Government would compel its rivals in commerce to obey." 659 F.2d at 247. But as then-Judge Ginsburg noted, "redress for [this] alleged grievance entails a policy judgment . . . [A] court should not infer such a judgment from the silence of Congress." *Id.* There is a strong public policy argument against jeopardizing the Red Cross's ability to carry out its critically important Congressional mandate to prevent and alleviate human suffering (36 U.S.C. §§ 300101–300102) by exposing it to substantial and unwarranted litigation costs under the antitrust laws, including possible treble damages and attorney's fees.

No case has ever held that an entity Congress formally designated as a federal instrumentality for all purposes, with all the rights consistent with that status, is a "person" within the meaning of the Sherman Act, much less an entity that Congress has assigned national and international public responsibilities, that operates as a non-profit, and whose designation Congress formally changed post-*Flamingo* and *McCarthy*. This Court should not be the first to break with precedent: the Red Cross is not a "person" under the Sherman Act.

II. VERAX DID NOT FIX OTHER FATAL FLAWS IN ITS ANTITRUST CLAIMS

Regardless of whether the Red Cross is a "person" under the Sherman Act, the Court should dismiss the complaint due to other fundamental deficiencies with Verax's antitrust claims.

Most importantly, Verax does not compete with the Red Cross in any cognizable antitrust sense for the same hospital business, and its opposition fails to grapple with this intractable flaw. Even setting aside the myriad physical and practical ways in which the Red Cross and Verax do not sell competing products, the FDA's 2016 regulations make competition between the Red Cross and Verax in a market for "bacteria mitigation services" **legally impossible**. The regulations do this in two keys way. *First*, they require the Red Cross to mitigate the risk of bacterial contamination in platelets *before* the Red Cross can sell those platelets to hospitals—and before those hospitals can even consider using PGD*prime* to extend those platelets' shelf-life. 21 C.F.R. § 606.145(a) ("[b]lood collection establishments" like the Red Cross must "assure that the risk of bacterial contamination … is adequately controlled;" and blood centers must do so using "FDA approved or cleared devices" or "other adequate and appropriate methods found acceptable for this purpose by FDA."). *Second*, the regulations (and FDA guidance) do not permit the use of Verax's PGD*prime* as a standalone method of bacterial mitigation. Although the FDA approved three methods of bacterial mitigation that blood centers may choose from to satisfy their obligations under the 2016 regulations (PRT, LVDS and a primary culture), the FDA regulations and affiliated

guidance do not approve PGD*prime* as an independently sufficient way for either blood centers or hospitals to mitigate bacterial risk.[5] Verax concedes this.

This means that PGD*prime* has only a very narrow, aftermarket role to play in the broader platelet ecosystem. It also means that the Red Cross and Verax operate at completely different levels of the supply chain. While Verax sells a product that hospitals can use to *supplement* what the Red Cross provides, customers cannot use PGD*prime* to *replace* anything the Red Cross sells.

None of these facts are in dispute.[6] The complaint itself incorporates the FDA regulations and guidance by reference (which are themselves publicly available official records). Compl. (ECF No. 1) ¶¶ 53–54. Yet Verax's brief simply pretends this situation does not exist. That is not surprising. Against the backdrop of the FDA regulations, no matter how Verax tries to define the product that the Red Cross sells, or the relevant markets for this case, Verax cannot allege the facts necessary to show that its aftermarket rapid test, PGD*prime*, competes against the Red Cross in any of those markets. Without this, Verax cannot state a claim under the antitrust laws.

A. Verax Admits It Cannot Establish Antitrust Injury Unless PGD*prime* Competes Against The Red Cross's Product In A Market For "Bacteria Mitigation Services," But Fails To Make That Showing

Verax does not dispute that, in this Circuit, only competitors (or customers) of a defendant *within an allegedly restrained market* are presumed to have an antitrust injury. Nor could it: that law is well-settled. *See*, *e.g.*, *Serpa Corp. v. McWane, Inc.*, 199 F.3d 6, 10–11 (1st Cir. 1999); *see also SAS of P.R., Inc. v. P.R. Tel. Co.*, 48 F.3d 39, 44–46 (1st Cir. 1995).

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[5] *See* FDA GUIDANCE FOR INDUSTRY, BACTERIAL RISK CONTROL STRATEGIES FOR BLOOD COLLECTION ESTABLISHMENTS AND TRANSFUSION SERVICES TO ENHANCE THE SAFETY AND AVAILABILITY OF PLATELETS FOR TRANSFUSION (Dec. 2020), https://www.fda.gov/media/123448/download.

[6] *Alt. Energy, Inc. v. St. Paul Fire & Marine Ins. Co.*, 267 F.3d 30, 33 (1st Cir. 2001) (a district court may consider official public records, among other things, in deciding a 12(b)(6) motion).

Verax, however, contends that its complaint should survive even though the allegedly restrained market that it now defines in its opposition—"bacteria mitigation services"—does not even appear to include Verax and its own product, PGD*prime*, within it. Opp at 13–14. Verax also does not explain how hospitals could lawfully substitute Verax's aftermarket rapid test for the treated or tested platelets that the Red Cross sells, without violating the requirements of the FDA's regulations. Verax only alleges that the Red Cross's upstream purchases of Cerus's INTERCEPT blood system technology (and decision to apply PRT to its platelets) reduced Verax's downstream sales of PGD*prime*. Opp at 10, 15–16. But this does not mean that Verax and the Red Cross compete in a market for sales of "bacteria mitigation services" to hospitals or that Verax has alleged an antitrust injury from the Red Cross's use of PRT.

1. In Trying To Bring The Red Cross's Sale Of PR-Platelets Into A Market For "Bacteria Mitigation Services," Verax Redraws The Market In A Way That No Longer Includes Its Own Product

First, Verax is wrong that it can establish antitrust injury without plausibly alleging a market for bacteria mitigation services that encompasses *both* PGD*prime* *and* the Red Cross's products. First Circuit law is very clear about this requirement: to allege an antitrust injury, a plaintiff must allege that it is "a participant in the *very* market where competition is impaired"—that is, where the defendant's alleged anticompetitive conduct took place. *SAS*, 48 F.3d at 44 (emphasis added); *Cf. In re Aluminum Warehousing Antitrust Litig.,* 833 F.3d 151, 160–63 (2d Cir. 2016) (citing *SAS* and explaining that, to establish antitrust injury, it is not sufficient that a plaintiff participates in some market in which the defendant also participates, or participates in some market where the effects of anticompetitive conduct may be indirectly felt—the parties must participate directly as competitors in the allegedly restrained market). If the plaintiff does not participate directly in the "very market" where the alleged anticompetitive conduct took place, there is no antitrust injury. *SAS*, 48 F.3d at 44 (explaining that a downstream supplier typically

does not suffer antitrust injury when upstream manufacturer acts anticompetitively towards supplier's customers even if that misconduct causes supplier to lose business from customers who otherwise would have purchased supplier's product; in that scenario, supplier does not participate in "very market" where competition is harmed).

As Verax's brief makes clear, it cannot meet this test.[7] It is telling that Verax has now changed the definition of "bacteria mitigation services" multiple times and yet still has not found a way to frame the market, at any level of the supply chain, to include *both* the Red Cross's sale of bacteria-mitigated, FDA-compliant platelets *and* Verax's sales of PGD*prime*. Each of Verax's formulations inevitably omits one or the other. For example, if, as the complaint suggests, "bacteria mitigation services" means the equipment and technology that the FDA has approved for hospitals or blood centers to buy to perform mitigation, then Verax may sell that product and compete in that market via PGD*prime*, but the Red Cross indisputably does not and never has. *See* Red Cross Mem. (ECF No. 19) at 7, 13, 15; Compl. ¶¶ 63–92. Verax admits that the Red Cross *buys* (not sells) the technology, devices and testing kits for bacterial mitigation. Compl. ¶¶ 114, 278; *see id*. ¶¶ 64, 76.

On the other hand, if as Verax now contends in its brief, "bacteria mitigation services" refers to the *application* of "FDA-endorsed services" to "platelets to reduce the risk of bacterial contamination," then *Verax is the one who does not participate as a seller in that allegedly restrained market,* even if the Court accepts for argument's sake that the Red Cross (and any other blood center that sells platelets in compliance with the FDA regulations) does. Opp. at 10; Compl.

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[7] Verax wrongly accuses the Red Cross of challenging its market definition on this motion. The Red Cross has not taken a position on market definition at all at this stage (but reserves its right to do so later). Verax's problem is that it never alleged facts that the Red Cross and Verax *both* participate as competing sellers in any "bacteria mitigation services" market, however defined. Thus, it cannot show antitrust injury.

¶¶ 82–88. Verax does not sell any service to hospitals which involves Verax applying PGD*prime* to platelets, as Verax admits. Compl. ¶ 86–88 ("[PGD*prime*] is performed by hospital transfusion service staff . . . . on the day of the transfusion[.]"). And no hospital can use PGD*prime* as a standalone way to satisfy FDA safety requirements. *See supra.*

This is not, as Verax suggests, an unimportant technicality that the Court may simply move past. It is a critical part of the governing standard for antitrust injury because it limits the availability of recovery to the categories of plaintiffs whom Congress intended to have it. *Cf. Serpa*, 199 F.3d at 9–12 (downstream distributor of defendant's product was not defendant's competitor in the allegedly restrained market and thus could not establish antitrust injury based on its role as a commercial intermediary at a different point in the supply chain); *W. Penn. Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 101–02 (3d Cir. 2010) (upstream supplier to insurers could not establish antitrust injury based solely on insurer's alleged anticompetitive restraints downstream, even if the supplier lost business as a result, where supplier and insurer did not compete by selling comparable products in allegedly restrained market). Verax does not cite a single case suggesting otherwise.

2. The FDA's Regulations Belie Verax's Claim That Hospitals Use PGD*prime* To "Substitute" For The Red Cross's FDA-Compliant Platelets

Verax nevertheless argues (without authority) that the Court should ignore its failure to articulate any tied market for "bacteria mitigation services" that encompasses the products that the Red Cross and Verax both sell because, as a "functional" matter, hospitals view the Red Cross's use of PRT as interchangeable with Verax's aftermarket rapid test—and can substitute these "products" for one another. But Verax does not allege any facts that support this. At the very least, the complaint had to offer a plausible explanation for how hospitals could replace the Red Cross's use of *any* bacteria mitigation method with Verax's PGD*prime* rapid test, given that doing

so is not legally possible as a result of the FDA's 2016 regulations. Verax did not do that. Instead, it ignores the implications of the FDA regulations altogether. To accept Verax's argument about substitutability is to believe that the Red Cross could sell platelets to hospitals without any bacteria mitigation performed on them at all. Opp. at 2–4. In this imaginary world, hospitals could choose between buying platelets that blood centers already tested or treated for bacterial contamination—such as platelets treated with PRT or tested with LVDS or a primary culture—*or* they could buy *untested* platelets and later test them exclusively with PGD*prime*.

That world does not exist—the FDA regulations ensure that.[8] It is against the law for the Red Cross to sell completely untested or untreated platelets to hospitals. It is likewise against the law for hospitals to buy untested or untreated platelets from the Red Cross and instead apply a PGDp*rime* rapid test as the hospital's sole form of bacteria mitigation prior to transfusion.[9] Ignoring this, Verax argues that because hospitals stopped buying as many PGD*prime* rapid tests to extend the shelf-life of platelets after the Red Cross began using PRT, the Court must assume that PGD*prime* is a substitute for the Red Cross's use of PRT in its platelet manufacturing process. But Verax's downstream commercial woes do not prove anything about the existence of a

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[8] The complaint makes this clear when it defines what it does—and does not—mean when it refers to "untreated" platelets. In the parlance of the complaint, "treated" platelets are merely platelets treated with PRT. According to Verax, if a platelet has not been subjected to PRT, it is untreated. "Untreated platelets," however, does not mean that those platelets are *untested, unmitigated* or non-FDA compliant. So-called "untreated" platelets have still undergone some other form of approved bacterial mitigation (such as LVDS or a primary culture), performed by a blood center, before they are sold to hospitals. *See, e.g.,* Compl. ¶ 93 ("ARC sold PRT platelets as well as untreated platelets that had been tested with either a Primary Culture or LVDS").

[9] This is true irrespective of whether the Red Cross opts to use PRT, LVDS or primary culture as its preferred bacteria mitigation strategy. Verax makes much of the fact that the FDA regulations do not require the Red Cross to use *PRT* specifically, but that misses the point. The Red Cross must use *some* form of bacteria mitigation in its manufacturing process. Because PGD*prime* cannot replace *any* form of bacteria mitigation the Red Cross chooses to use, Verax cannot allege that PGD*prime* competes against the Red Cross's application of bacteria mitigation technology to platelets, regardless of which method the Red Cross uses.

competitive relationship between the parties. A company's allegations that its aftermarket product is not compatible with another company's new or improved product —and that the supplier's share of the aftermarket suffered as a result—does not, without more, suggest the existence of competitive injury that the antitrust laws were designed to solve.

Verax's analogies miss the mark. Verax argues PGD*prime* is a competitive substitute for the Red Cross's FDA-compliant platelets because, in a different context, Covid-19 patients can use at-home rapid tests instead of going to an in-person testing center. But these situations differ in a critical respect. Today's FDA regulations do not require consumers to obtain a Covid test from an in-person Covid-19 clinic *before* they are approved to purchase, use and rely upon the results of an at-home rapid test. Without that fact, Verax's analogy is meaningless here. The Court should dismiss Verax's Sherman Act claims for failure to plead antitrust injury.

B. Under Verax's Attempted Reframing of The "Tying" and "Tied" Markets, The Red Cross Does Not Sell *The Tying Product*—Count One Thus Fails

Verax's attempts to remedy the other problems with its Section 1 tying claim fare no better. As Verax admits, the type of tying claim it alleges requires allegations that the Red Cross used its power over a "tying product" to coerce a customer to purchase the second "tied product." *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 12 (1984). Thus, Verax had to allege facts showing that the Red Cross actually sells both a "tying" and a "tied" product.

As the Red Cross previously pointed out, Verax does not allege that the Red Cross sells any technology or physical devices used to perform bacteria mitigation. Red Cross Mem. at 13, 15; Compl. ¶¶ 63–92, 114, 278.[10] In Verax's newest telling, however, the "tied" product—

[10] Instead, Verax accuses the Red Cross of arguing a very different point—whether mitigated platelets and bacteria mitigation services are one product rather than two. But, as the Red Cross made clear in its opening brief (Red Cross Mem. at 15), the Court does not need to reach that question now. And that makes Verax's lengthy discussion of *United States v. Microsoft,* 253 F.3d

"bacteria mitigation services"—refers to the *application* of "FDA-endorsed services" to platelets to reduce the bacterial risk. This necessarily means that the "tying" product, previously defined as platelets *already* treated or tested with some form of bacteria mitigation technology, now can only logically refer to platelets not yet subjected to any bacteria mitigation process ***at all*** (without collapsing the separate tied and tying product categories entirely together). Opp. at 1, 10. This is not what the complaint alleges, but it is the only way to make sense of Verax's opposition brief.

But this reformulation does not help Verax; it simply trades one fatal defect for another. Using this new version, if unmitigated platelets are now supposed to be the "tying" product in this case for purposes of the complaint, then the Red Cross does not sell that product either—and cannot do so as a matter of law under the FDA regulations. Because Verax fails to allege that the Red Cross sells the newly-defined *tying* product at all, it has not alleged a tying violation. *Jefferson Parish,* 466 U.S. at 12. Count One must be dismissed.

C. Verax Fails To Allege Any Reduced Competition Between The Red Cross And Any Competitor; Counts Two And Three Therefore Fail

Verax also failed to allege that the Red Cross's use of PRT has harmed competition in any alleged market for bacteria mitigation services (however defined) by, for example, reducing the nature or number of competitors in the purported market. *See, e.g., E. Food Servs., Inc. v. Pontifical Cath. Univ. Servs. Ass'n,* 357 F.3d 1, 8 & n.4 (1st Cir. 2004)*; Sterling Merch., Inc. v. Nestle, S.A.*, 656 F.3d 112, 123–26 (1st Cir. 2011) (exclusive dealing and Section 2 monopoly claims required showing that the alleged conduct "impaired the competitiveness of the market").

Verax's only argument is that because the Red Cross's use of PRT has allegedly reduced *Verax's* aftermarket sales, the court may rely on *Verax's own alleged* harm as being indicative of

34 (D.C. Cir. 2001) irrelevant. Assuming solely for this motion that they are two products, Verax still had to allege that the Red Cross actually makes and *sells both of them*. It did not do so.

broader harm to competition. But Verax has not competently alleged that it (or bioMérieux) competes against the Red Cross in any relevant market for "bacteria mitigation services," so its own commercial struggles selling PGD*prime* do not—without more—suggest that the Red Cross's conduct has harmed competition in any such market. *Sterling*, 656 F.3d at 123–25.

Verax next argues that the Court can find harm to competition because the Red Cross's use of PRT will result in higher prices for customers. But even if this were true, higher prices do not, without more, show harm to competition. *See CCBN.Com, Inc. v. Thompson Fin.,* 270 F.Supp.2d 146, 155 (D. Mass. 2003) (Saris, J.) (explaining that higher prices do not themselves suggest harm to competition absent allegations regarding competitors and the competitive structure of the market). Verax needed to allege **something** to support that PRT's allegedly higher prices resulted from an impairment to the competitive structure of the market. It failed to do that.

III. VERAX FAILS TO STATE ANY CLAIM UNDER MASSACHUSETTS LAW

A. None Of Verax's After-The-Fact Arguments Save Its Defamation Claim

Verax does not deny that it has failed to plausibly allege a critical component of its defamation claim: whether the Red Cross's statements are "reasonably susceptible of defamatory meaning" as to *Verax.* None of the Red Cross's alleged statements are about Verax directly and none of those about PGD*prime* remotely imply that *Verax itself* is dishonest, lacks integrity, or has deliberately perpetrated a fraud on the public. *HipSaver, Inc. v. Kiel*, 984 N.E.2d 755, 762 n.6 (Mass. 2013). Verax asks the Court to ignore all of that, because, in Verax's view, "the proper time to make [the defamatory-meaning] determination" is "after discovery." Opp. at 20. But that is not Massachusetts law. *See Shay v. Walters*, 702 F.3d 76, 81, 82–83 (1st Cir. 2012) (issue is threshold question proper for Rule 12 disposition). Because Verax failed to allege that the Red Cross's statements were defamatory of *Verax*, Verax's claim fails as a matter of law.

The Court should reject Verax's invitation to pretend that the complaint actually pled a completely different tort—one for commercial disparagement. The complaint contains no commercial disparagement count, and such a claim imposes "even more stringent [pleading] requirements" on the plaintiff, including requiring allegations of "special damages"—which Verax has not even attempted to meet. *HipSaver, Inc.*, 984 N.E.2d at 763 n.7, 771, 772 (unlike in a claim for defamation, a plaintiff claiming commercial disparagement must allege "special damages" in the form of a "specific loss of sales to identifiable customers") (citations omitted). For this reason, courts have explicitly refused to allow plaintiffs to commit this kind of end-run around the pleading requirements of defamation and commercial disparagement claims. *See Peaceable Planet, Inc. v. Ty, Inc.*, 362 F.3d 986, 993–94 (7th Cir. 2004) (Posner, J.) (explaining that "product disparagement and defamation are distinct torts" and affirming dismissal of plaintiff's product-disparagement count since it sounded in defamation, not product disparagement, and "the complaint contain[ed] no defamation count"). The Court should dismiss Count Five.

B. Verax Is Wrong That Its Tortious Interference Claim Can Survive Without Allegations That Any Specific Contractual Relationship Was Breached

Verax's tortious interference with contractual relations claim fails for a similar reason. Massachusetts law is very clear: if a complaint fails to "identify any *specific* contract, relationship or opportunity that was lost as a result of [the defendant]'s conduct," a tortious interference with contract claim cannot survive dismissal. *Sensitech Inc. v. LimeStone FZE*, 548 F.Supp.3d 244, 258 (D. Mass. 2021) (emphasis added); *Curley v. Softspikes, LLC*, 2010 WL 2545611, at *3 (D. Mass. June 21, 2010) (dismissing claim where "Plaintiffs make only the conclusory allegation that Defendants contracted directly with unidentified parties who otherwise would have contracted with Curley"). Ignoring this fact, Verax instead argues that it need not have identified any contractual relationship to properly allege a tortious interference *with contractual relations* count,

because all it had to do was "simply identify the 'opportunity that was lost.'" Opp at 19. Verax says it did this by alleging that Verax lost some unidentified number of hospital customers based on ARC's actions. But this is not the law for the claim in the complaint. Verax did not identify any specific contract that it has with any hospital, much less one that a hospital breached (or that Verax lost) because of anything the Red Cross did. Count Six fails.

C. Verax Cannot Deny That Its Derivative Chapter 93A Claim Fails

Finally, Verax does not deny that its Chapter 93A claim necessarily fails where its underlying antitrust and Massachusetts state law claims fail too. *See Skehel v. DePaulis*, 2017 WL 2380164, at *2 (D. Mass. June 1, 2017) (explaining that where "Chapter 93A claims are derivative of . . . unsuccessful claims . . . , they cannot succeed"). Verax's Chapter 93A claim independently fails because the complaint affirmatively alleges that the Red's Cross's alleged unfair conduct did *not* "occur[] primarily and substantially within the [C]ommonwealth." *Kuwaiti Danish Comput. Co. v. Digit. Equip. Corp.*, 781 N.E.2d 787, 798–99 (Mass. 2003). Specifically, the complaint precludes a finding that the antitrust claims have any "center of the gravity" in the Commonwealth, despite the alleged location of Verax's injuries, because Verax has alleged that the relevant antitrust geographic market *is the United States. See, e.g.*, Compl. ¶¶ 190, 203–204; *Fishman Transducers, Inc. v. Paul*, 684 F.3d 187, 197 (1st Cir. 2012) ("Where wrongdoing is not focused on Massachusetts but has . . . substantial impact across the country, the 'primarily' requirement . . . cannot be satisfied."). Nor does Verax suggest a different location for the events underlying its state law claims. Count Four thus fails.

The Court should dismiss Verax's complaint in its entirety.

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Respectfully submitted,

/s/ William J. Trach
William J. Trach (BBO # 661401)
LATHAM & WATKINS LLP
200 Clarendon Street
Boston, MA 02116
Telephone: (617) 948-6000
Facsimile: (617) 948-6001
william.trach@lw.com

Amanda P. Reeves (*pro hac vice*)
Jennifer L. Giordano (BBO # 650537)
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004
Telephone: (202) 637-2200
Facsimile: (202) 637-2201
amanda.reeves@lw.com
jennifer.giordano@lw.com

Alfred C. Pfeiffer (*pro hac vice*)
LATHAM & WATKINS LLP
505 Montgomery Street, Suite 2000
San Francisco, CA 94111
Telephone: (415) 391-0600
Facsimile: (415) 395-8095
al.pfeiffer@lw.com

Attorneys for Defendant
American National Red Cross

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document, which was filed with the Court through the CM/ECF system, will be sent electronically to all registered participants as identified on the Notice of Electronic Filing ("NEF") and paper copies will be sent on June 13, 2023 to those identified as non-registered participants.

/s/ William J. Trach
William J. Trach